

## REMARKS

Claims 11-19, 32-36, and 38-41 were pending in the application. By this amendment, claims 11, 15, and 32 have been amended. Reconsideration and withdrawal of the rejections is requested in view of the foregoing changes to the claims and the following remarks.

The following remarks are intended to address all of the grounds for rejecting the claims set forth in the pending Office Action.

### Rejections under 35 U.S.C. §102(e)

Claims 11-19 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Deem et al. (U.S. Patent No. 6,558,400).

In response, claim 11 has been amended to recite that the claimed method includes the steps of “piercing the first tissue fold with a needle defining a lumen” and “ejecting a first anchor from the needle across the first tissue fold.” Similarly, claim 15 has been amended to recite that the claimed method includes the steps of “piercing at least one of the first plurality of tissue folds with the needle” and “ejecting a first anchor from the needle across the at least one tissue fold.” Support for these amendments is provided in the specification at, for example, paragraphs 0154-0157, and at Figures 21A-G. Figure 21C is illustrative and is reproduced below:

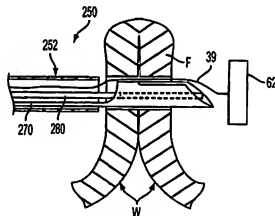


FIG. 21C

These features reflect a significant difference between the methods described and claimed in the present application and the method taught and suggested in the Deem patent. In particular, the method illustrated in Figure 28 of the Deem patent includes applying a ligating device 478 that is intended to tie or ligate tissue withdrawn by a forceps 476. (Deem, col. 19, ll. 35-44). This is far different from Applicant's claimed method of "piercing" a tissue fold with a needle and "ejecting a first anchor" from the needle across the tissue fold. Nowhere does Deem teach or suggest these method steps, or even a device capable of performing these method steps.

Nor would it have been obvious to modify the Deem method to include the method steps recited in claims 11 and 15. In the Deem method, the ligated tissue is either excised and removed using the forceps, or removed naturally by pressure necrosis. (Deem, col. 19, ll. 45-54). Applicant's methods for forming, approximating, and securing tissue folds would not result in and do not contemplate tissue removal via ligation. These are very different processes that produce very different results.

For these reasons, there can be no anticipation of claims 11 or 15 by the Deem patent. Claims 12-14 each depend from claim 11, and claims 16-19 each depend from claim 15. As a result, these claims are not anticipated by the Deem patent for the same reasons set forth above. Accordingly, Applicant requests withdrawal of the rejections of these claims.

#### **Rejections under 35 U.S.C. §103(a)**

Claims 32-36 and 38-40 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Deem patent in view of Matsui et al. (U.S. Patent No. 6,352,503). Applicant responds as follows.

As to the grounds for rejection, Applicant disagrees with several of the contentions stated in the Office Action to support the obviousness rejections. First, the Office Action states (at page 4) that the Deem patent discloses a method that includes the steps of "advancing a plication apparatus (e.g., an endoscopic vacuum-type device 280 as seen in figure 15A) within a patient's stomach; approximating and deploying tissue anchors (110) through each of first and second pluralities of tissue folds." To make this

contention, the Office Action relies on two mutually exclusive embodiments of the Deem device. First, there is the “endoscopic vacuum-type device 280 as seen in figure 15A”:

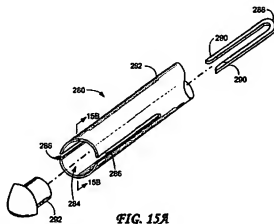


FIG. 15A

Second, there are the “tissue anchors (110)” which are shown in Figures 6A-B:

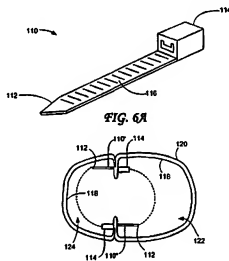


FIG. 6B

But there is nothing in the Deem patent that teaches how the “tissue anchors (110)” could be deployed using the “endoscopic vacuum-type device 280.” Instead, the approximating device 280 shown in Figure 15A is used with an “approximating clip 288.” (See Deem, col. 13, line 33 to col. 14, line 9). As a result, there can be no prima facie case of obviousness.

Second, the Office Action states (at page 4) that Matsui discloses “advancing an overtube (101) through a patient’s esophagus into the patient’s stomach while the overtube is disposed in a flexible state; transitioning the overtube to a rigid state (at 111)

in a desired orientation.” Applicant respectfully disagrees with this contention. Nowhere does Matsui teach or disclose anything about transitioning any part of the overtube to a rigid state, nor does the Office Action identify any specific teaching of this feature contained in the Matsui patent. Once again, this failure to support the grounds for rejecting these claims means that there can be no prima facie case of obviousness.

Despite these errors in the Office Action, and in order to expedite prosecution, claim 32 has been amended to recite that the overtube includes “a plurality of nestable elements” and that the recited method includes the step of “imposing a clamping load on the plurality of nestable elements of the overtube to transition the overtube to a rigid state in a desired orientation within the patient’s stomach.” Support for these amendments is provided in the specification at, for example, paragraphs 0230-0233, and at Figures 35-39. Figures 35 and 36 are reproduced below and illustrate an embodiment of an overtube 1002 having a plurality of nestable elements 1010 that are configured to be clamped together via a tensioning wire 1016:

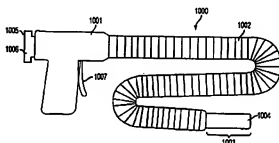


FIG. 35

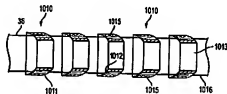


FIG. 36

Neither the Deem patent nor the Matsui patent teaches any of these features. As a result, claim 32 is patentable over the combination of Deem and Matsui. The other rejected claims – claims 33-36 and 38-40 – are patentable on the same grounds.

Finally, claim 41 was rejected as allegedly being unpatentable over the combination of Deem and Matsui in further view of Harrison (U.S. Patent No.

5,403,326). As noted above, claim 32 (from which claim 41 depends) is patentable over the combination of Deem and Matsui. The Harrison patent does not provide the subject matter missing from the Deem and Matsui patents.

Accordingly, the combination of Deem, Matsui, and Harrison fails to disclose all of the features of Applicant's claims. There is, therefore, no prima facie case of obviousness. Applicant requests withdrawal of the rejection and allowance of claims 32-36 and 38-41.

For the foregoing reasons, Applicants request withdrawal of the rejections of all pending claims, and issuance of a Notice of Allowance.

Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Similarly, unless explicitly stated, nothing contained or not contained in this paper should be construed as an assent to any of the Examiner's stated grounds for rejecting the claims, including specifically the Examiner's characterization of the teachings of the cited art and the Examiner's contentions that any combinations of cited art would have been obvious. Rather, the present amendments to the claims and Remarks are an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added

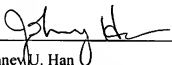
Application No.: 10/734,547  
Examiner: Julian W. Woo  
Attorney Dkt. No.: USGINZ02511

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02511**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

  
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